

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



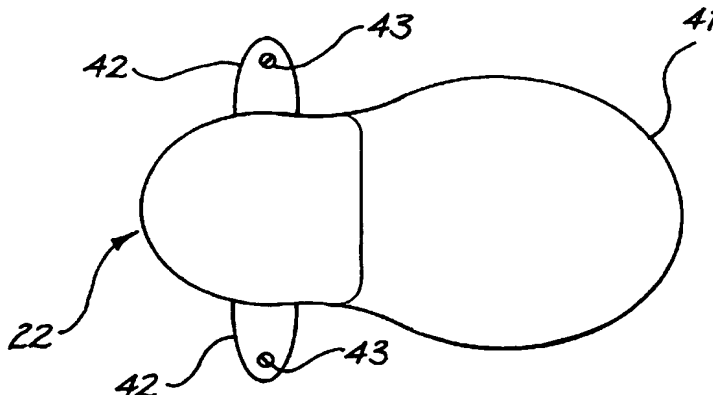
(43) International Publication Date
19 February 2004 (19.02.2004)

PCT

(10) International Publication Number
WO 2004/014269 A1

- (51) International Patent Classification⁷: **A61F 11/00**, (74) Agent: **F B RICE & CO**; 605 Darling Street, Balmain, NSW 2041 (AU).
A61B 17/56
- (21) International Application Number: PCT/AU2003/001004
- (22) International Filing Date: 8 August 2003 (08.08.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
2002950755 9 August 2002 (09.08.2002) AU
- (71) Applicant (for all designated States except ¹US): **COCHLEAR LIMITED** [AU/AU]; 14 Mars Road, Lane Cove, NSW 2066 (AU).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **GIBSON, Peter** [AU/AU]; 16 Marcel Avenue, Randwick, NSW 2031 (AU). **JOHANSEN, Lars, Vendelbo** [DK/DK]; ENT-Department, Aarhus University Hospital, DK-800 Aarhus C (DK).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **FIXATION SYSTEM FOR AN IMPLANTABLE MEDICAL DEVICE**



(57) Abstract: A medical implant, such as an implantable component (22) of a tissue-stimulating prosthesis. One example of such a prosthesis being a cochlear implant. The component (22) is adapted to be implanted at or adjacent a tissue surface within the recipient, such as a bone surface. The component (22) has a housing and at least one flange (42) extending outwardly therefrom. The flange (42) can be secured to the tissue surface via a tissue fixation device, such as a bone screw (43).

BEST AVAILABLE COPY

WO 2004/014269 A1

"Fixation system for an implantable medical device"

Field of the Invention

5 The present invention resides in an improved method of mounting an implantable component of an implantable medical device, such as a cochlear implant package, securely in the head region of a recipient.

Background of the Invention

10

 In many people who are profoundly deaf, the reason for deafness is absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is
15 damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

 It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to
20 the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

 Cochlear implant systems have typically consisted of essentially two components, an external component commonly referred to as a processor unit and an
25 internal implanted component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to a user.

 The external component has traditionally consisted of a microphone for
30 detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter antenna coil.

 The coded signal output by the speech processor is transmitted transcutaneously
35 to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the user. This transcutaneous transmission occurs via the external transmitter

antenna coil which is positioned to communicate with an implanted receiver antenna coil provided with the receiver/stimulator unit.

5 This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

10 The implanted receiver/stimulator unit traditionally includes a receiver antenna coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlear electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected
15 sound.

Traditional implanted receiver/stimulator units are positioned within the head of the recipient by drilling a bed into and through the posterior section of the mastoid bone lying behind the recipient's ear. Such a bed is usually made by drilling the bone down
20 to the lining of the brain or dura mater, so that the receiver/stimulator unit is maintained in position and does not protrude excessively past the skull surface.

The receiver/stimulator unit manufactured by the present Applicant has a package made from titanium which houses the stimulation electronics and which is
25 fitted into a bed created in the mastoid bone. A receiver antenna coil extends from the rear end of the package and lies superficial to the bone. Other cochlear implants have included packages made from a ceramic material which are usually placed completely within the bed drilled down to the dura mater.

30 Various techniques have been implemented in order to mount or fix the device in place and to ensure that the device does not undergo movement once implanted.

One such technique has been to drill holes in the bone surrounding the device and to use sutures or Dacron ties to hold the device in place. One problem with this
35 approach is that drilling of the holes into the surrounding bone can be a difficult and time consuming procedure, and especially for young children, much care must be taken

by the surgeon to ensure that the drilling does not perforate the dura mater, as the skull thickness in such cases can be quite thin. Further to this, the suture or Dacron ties may not be sufficiently strong enough to withstand a substantial impact to a region of the head adjacent the device and as a result, such a force may dislodge the device from its desired position. In addition, it has been found that if a suture or Dacron tie is inadvertently placed across an inappropriate section of the device, such as across a strain relief of the electrode lead, the suture/tie may cause the lead/device to undergo fatigue and cause failure at this location.

Another technique used to secure the implant device in place is for the surgeon to craft a suitable well or bed in the cranial bone that is capable of maintaining the device in place without the need of sutures or ties. Such a technique relies upon the shape of the well or bed being such that the surrounding bone can hold the device in place. This technique is not always possible depending upon the thickness of the surrounding bone and the age and anatomy of the recipient.

Therefore, there is a need to provide a fixation method for an implantable hearing prosthesis that is capable of securely maintaining the device in place in a desired region of the recipient's head without the need for additional sutures or ties.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is a medical implant for implantation within a body of a recipient, the medical implant comprising a

hermetically sealed housing, said housing having at least one flange extending outwardly therefrom that is securable to tissue within the body of the recipient.

In this aspect, the flange can be securable to a suitable tissue surface. While a bone surface is preferred, it can be envisaged that the flange could be securable to a
5 other suitable tissues within the body, including cartilage and tendons.

In one embodiment, the implant can be an implantable component of a tissue-stimulating prosthesis. In a preferred embodiment, the tissue-stimulating prosthesis is a cochlear implant. The implantable component of the cochlear implant preferably
10 comprises a receiver/stimulator package of such an implant. While the present application will hereinafter refer to cochlear implants, it is to be understood that the invention has a potential wider application to other implantable tissue-stimulating prostheses.

15

In one embodiment, the housing of the implantable component can be adapted to be placed on the surface of the bone of the recipient. In the case of a cochlear implant, this bone would likely be the mastoid bone. In another embodiment, a bed or well can be formed in the surface of the bone, such as the mastoid bone, such that the housing
20 can be positioned in the well or bed.

In one embodiment, a flange can extend outwardly from the housing in at least one direction. More preferably, the housing has at least two flanges extending outwardly therefrom. In this embodiment, the flanges preferably extend in
25 substantially opposite directions relative to each other. In a further embodiment where there are two flanges, the respective flanges can extend in opposite directions relative to each other.

In one embodiment, at least one flange preferably extends from a first or upper
30 surface of the housing. The first surface of the housing is preferably the outer surface of the housing on implantation of the component.

In another embodiment, at least one flange can extend from a second or lower surface of the housing. In this embodiment, the second surface preferably faces
35 inwardly, such that the surface normally abuts with or is embedded in the bone of the recipient receiving the implantable component.

In a still further embodiment, at least one flange can extend from the housing at a location between the first and second surfaces of the housing. In one embodiment, the flange can extend outwardly from a location that is approximately midway between
5 the first and second surfaces.

In yet another embodiment and where there is more than one flange, one of such flanges may extend from the first or upper surface while another extends from the second or lower surface. Other flange combinations can be envisaged.

10

In a further embodiment, the flanges extending from the housing comprise part of a plate mounted to the housing of the implantable component. In one embodiment, the plate can be removably or non-removably mounted to the housing.

15

Each of the flanges are preferably adapted to abut the tissue surface of the recipient following implantation of the implantable component. In one embodiment, the flanges are preferably conformable to the tissue surface. In this regard, the flanges can be formed from a malleable material that allows the flanges to be conformed to the surface of the tissue, such as bone. In another embodiment, the flanges can be
20 constructed so as to be conformable to the tissue surface. In this regard, the flanges may have a thickness that allows the flanges to be suitably conformable during the surgical procedure. In a still further embodiment, both the properties of the material and the construction of the flanges may play a role in ensuring the flanges are malleable and conformable to the tissue surface. The flanges are preferably conformable by
25 finger pressure exercisable on the flanges by a surgeon during the surgical implant of the implantable component.

The degree of conformation of the flanges necessary to ensure the flanges conform to the tissue surface will depend on the position of the flanges and/or whether
30 the housing of the component is embedded within the tissue, such as within a well or bed within the bone. Where the flanges extend from the first surface of the housing, the downward angle of the flanges necessary so as to abut with the tissue surface will depend on the degree to which the housing is embedded within the tissue. The downward angle of the flange is likely to be less when the housing is at least partially
35 embedded in the tissue in comparison to the situation where the housing essentially is sitting on the tissue surface.

In one embodiment, the flanges can have a thickness between about 0.1mm and 0.3mm. The flanges can be formed from a malleable material.

5 In one embodiment, the flanges can constitute an integral extension of the housing of the implantable component. In another embodiment, the flanges can be formed separately and mounted to the housing. Techniques such as welding and brazing can be envisaged as techniques for mounting the flanges to the housing of the implantable component. In another embodiment, one or more flanges may be an
10 integral extension of the housing while one or more may be formed separately and mounted to the housing.

In another embodiment, the flanges can be removably mounted to the housing. In this embodiment, the flanges or housing of the implantable component can be
15 provided with engagement means adapted to engage with the housing or flanges, respectively. In one embodiment, the housing can have one or more clips adapted to engage with the flanges. In this embodiment, it is envisaged that the flanges may not be mounted to the housing until surgery is underway and the size and shape of the flanges required for that particular surgery have been determined. Still further,
20 removably mounted flanges provide the surgeon with the option of not using the flanges at all.

In one embodiment, the flanges can be formed of titanium, such as malleable titanium. In this and other embodiments, the housing of the implantable component
25 can also be formed from titanium. In another embodiment, the housing of the implantable component and/or the flanges can be formed of other materials, including suitable biocompatible metallic, ceramic and polymeric materials. In this regard, the flanges and housing do not need to be formed of the same material. For example, the flanges could be formed of a polymeric material, such as polypropylene or
30 polytetrafluoroethylene, while the housing is formed of a ceramics or metallic material.

As defined above, the flanges are preferably securable to the surface of the tissue within the recipient. In one embodiment, one or more of the flanges can have orifices passing therethrough. These orifices can be adapted to receive tissue fixation
35 devices, such as screws, clips and/or nails, including bone screws, bone clips and bone

nails. In one embodiment, the screws can be countersunk, or have a round head. Still further, the tissue fixation devices can be resorbable.

5 In one embodiment, the housing is preferably adapted to be secured to the tissue surface at the site of each flange. It will, however, be appreciated that there may be instances where it is not possible to use a particular flange due to a previous cavity having been formed in the selected tissue, or, for example, the presence of a skull growth line, or a region of bone weakness.

10 In the above embodiments, the flanges and/or housing can be coated with a layer of silicone rubber or other suitable elastomeric material. The tissue fixation devices would preferably be accessible by means of a slit or hole formed or formable in the coating material.

15 According to a second aspect, the present invention is a medical implant for implantation within a body of a recipient, the medical implant comprising a hermetically sealed housing, said housing having at least one flange extending outwardly therefrom that is securable and conformable to tissue within the body of the recipient.

20 In this aspect, the said at least one flange can be formed of a malleable material. In this aspect, the implant, housing and flange can have any one or more of the features defined herein with reference to the first aspect.

25 In the case of a cochlear implant, an electrically conducting lead preferably extends from the receiver/stimulator package to an electrode array. The lead preferably exits the package such that it is extendable into the cochlea of the recipient on appropriate positioning of the implantable component within the recipient. In a preferred embodiment, the lead preferably extends from the implanted package to the
30 cochlea via a posterior tympanotomy positioned at the bottom of a mastoid cavity. Other lead positions and geometries are can, however, be envisaged.

The present invention provides a housing of an implantable component having one or more flanges for use in securing the component to a tissue surface of the
35 recipient. In addition to supporting the component, the flanges have the additional characteristic of serving to protect the component from inadvertent dislodgment

following an impact that might otherwise dislodge the component if positioned and mounted using conventional techniques.

Brief Description of the Drawings

5

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

10

Fig. 1 is a pictorial representation of a conventional cochlear implant system;

Fig. 2 is a representation of a conventional receiver/stimulator unit positioned in a bed fashioned in the mastoid bone according to conventional surgical techniques;

15

Fig. 3 is a representation of a typical prior art method of fixing the receiver/stimulator unit in place during surgery;

Fig. 4 is a plan view of one embodiment of the present invention;

20

Fig. 5a is an end view of the embodiment shown in Fig. 4 mounted to a bone surface of a skull;

Fig. 5b is a side view of the embodiment shown in Fig. 4 mounted to a bone surface of a skull;

25

Figs. 6a and 6b are an end view and a side view, respectively, of the embodiment shown in Fig. 4 with the implant being sunk lower into the skull than that shown in Fig. 5a;

30

Figs. 7a and 7b are an end view and a side view, respectively, of an alternative embodiment of the present invention;

Figs. 7c and 7d are an end view and a side view, respectively, of yet another alternative embodiment of the present invention;

35

Figs. 8a and 8b are an end view and a side view, respectively, of yet another embodiment of the present invention;

Figs. 9a and 9b are an end view and a side view, respectively, of an alternative embodiment of the present invention;

5 Fig. 10 is an alternative embodiment of the present invention having detachable flange portions;

Figs. 11a and 11b are an end view and a side view, respectively, of the embodiment shown in Fig. 10;

10

Figs. 12a and 12b are an end view and a side view, respectively, of the embodiment shown in Fig. 10 where the implant has been sunk lower into the skull than that depicted in Figs. 11a and 11b;

15

Fig. 13 is yet another embodiment of the present invention having a detachable flange plate; and

Figs. 14a and 14b are an end view and a side view, respectively, of the embodiment shown in Fig. 13.

20

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of one type of known cochlear implant system with reference to Fig. 1.

25

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11 and is held in place behind the outer ear 11 via an ear-hook arrangement. Alternative versions may be worn on the body. Attached to the speech processor 29 via a cable 13 is a transmitter antenna coil 24 that transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

35

The implanted component includes a receiver antenna coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930.

Fig. 2 shows in more detail the surgical placement of the implanted receiver and stimulator package 22 of Fig. 1, according to conventional practices. The package 22 is in the form of a capsule, for example a titanium capsule, which houses the necessary circuitry required for the implant to operate as desired. The receiver antenna coil 23 is shown encapsulated in a material, such as silicone rubber, to provide a protective body and ensure fatigue resilience. A magnet 30 is shown positioned within the coil to assist in the alignment of the transmitter coil 24 with the receiver antenna coil 23 as discussed previously. As is shown, a bed is drilled into the bone 31 to maintain the package 22 in position. This bed is typically round or ovoid to match the shape of the package. The bed is typically made in the mastoid bone and mastoid angle of the parietal bone in the region of the asterion. Typically, the bed is fashioned initially with a cutting burr, and then completed with a diamond paste burr and a template is typically used to ensure that the bed is fashioned to the correct size. As is shown, the bed may be drilled down to the lining of the brain, or dura mater 32, particularly for young children with thin skulls, and it is for this reason that a diamond paste burr may be used when approaching the dura and when the dura is exposed, to minimise the risk of tearing of the dura 32.

As can be appreciated from Fig. 2, any impact in the direction shown by the arrow A of Fig. 2, has the potential for the package to tear the dura 32 and enter the cranial cavity, potentially causing damage to the sensitive structures of the brain. Further to this, an impact to the head region of the recipient, particularly in the direction shown by arrow B, has the potential to dislodge the implant from its bed within the skull bone. Such dislodgment can cause damage to the area of the head adjacent the device as well as discomfort to the recipient. Any dislodgment of the device also has the potential to require further surgical procedures to relocate the device in the desired position within the head of the recipient. Further to this, such dislodgment of the device may cause the location of the strategically positioned

electrodes of the electrode array to be altered, requiring possible re-implantation to rectify this problem.

Fig. 3 depicts a typical fixation technique used to secure the device 22 in place prior to wound closure during a surgical procedure. In such a technique, prior to fixation of the device 22, small tunnels 35 are drilled in the bone on either side of the package bed to place ties or sutures 36 to hold the receiver/stimulator package in place. As previously mentioned, in an infant, such a procedure is not recommended, as the bone is thin and the drill may abrade the dura. For children, one method of securing the device in place is to tie the device down with ligatures placed through the temporalis and deep fascia, and to also stitch the anteriorly based facial flap over the package.

One embodiment of the fixation system according to the present invention is shown in Figs. 4, 5a and 5b. In this embodiment, the implant package is once again shown by numeral 22, which preferably consists of a titanium casing enclosing the implant electronics. The silicone rubber material encapsulating the receiver coil is shown as 41, which in practice would encapsulate both the receiver antenna coil and a positioning magnet (not shown) as is known in the art. Two malleable flanges 42 are shown extending from the implant package 22. These malleable flanges 42 are suitably sized and shaped to be integrated with the implant package 22 so that the package 22 can be secured in place by securing the flanges to the skull via skull attachment devices 43 (ie. bone screws or pins). While depicted being securable to a bone surface, it will be appreciated that the present invention has application for mounting medical implants to other bodily tissues.

The malleable flanges 42 are preferably made from a titanium material and, in the depicted embodiment, are attached to the titanium implant package 22 by welding. Alternatively, the flanges 42 may be made integral with the implant package 22, and may merely be extension of the package 22. It is envisaged that other metals may be used for the implant package 22 and flanges 42, for example, any biocompatible metal such as stainless steel. It would, however, be preferable that the material used for the implant package 22 and/or flanges 42 be non-magnetic to allow MRI compatibility.

The skull attachment devices 43 are typically surgical screws and preferably have a low profile so they do not cause tissue erosion in the region of the head surrounding the implant, or produce a noticeable protuberance. Preferably, the flanges

42 and skull attachment devices 43 are coated in a silicone rubber to prevent tissue erosion, with the skull attachment devices 43 being accessed by means of a slit or hole in the silicone rubber above the skull attachment devices 43.

5 As shown in Figs. 5a and 5b, the flanges 42 are attached to the uppermost surface of the implant package 22, with part of the implant package 22, hereby referred to as the implant pedestal 44, being sunk into the skull. In these figures, the dotted line represents the line of the skull. It should be appreciated that in all embodiments shown the pedestal 44 is not essential to the invention, and is only shown here to illustrate that
10 the present invention is applicable to implants of variable configurations. It should also be appreciated that other such embodiments are possible and it is not necessary for the flanges 43 to be attached to the uppermost surface of the package 22, as the flanges 43 could be equally connected to other regions of the implant package 22.

15 As can be appreciated in Figs. 5a and 5b, the flanges 43 must be sufficiently robust and yet sufficiently malleable to enable them to be formed and manipulated to fit the shape of the recipient's skull. As this manipulation typically occurs during the surgical implantation procedure, it is important that the forces required to manipulate the flanges 43 can be performed by the surgeon using finger pressure only. As the
20 anatomy in this area of the head varies from patient to patient, it is desirable to form the flanges 43 so as to have a flush fit against the skull so as to maintain a low profile of the device and to reduce the occurrence of tissue erosion. In this regard, the flanges 43 would preferably only need to be manipulated to a relatively small degree.

25 As surgical methods and preferences vary from surgeon to surgeon, it is important that the present invention can also be adapted to meet such variations. As can be seen in Figs. 6a and 6b, some surgeons may prefer to partially sink the implant package 22 into the skull bone, with the dotted line in both figures representing the line of the skull. In such a case, the flanges 42 must be malleable to allow the surgeon to
30 bend them to the correct position to suit the preferred depth of the implant bed or well. By a direct comparison between the implants depicted in Figs. 5a and 5b and Figs. 6a and 6b, it can be seen that in the case where the implant package is sunk to a deeper depth (Figs. 6a and 6b), the angle (Φ), the downward angle with which the flanges 42 exit the implant package 22, can be adjusted accordingly. The angle (Φ) shown in Figs.
35 6a and 6b has been increased to compensate for the greater depth of the implant bed than that shown in Figs. 5a and 5b. This malleability characteristic can be achieved by

selection of the material and/or thickness and/or geometry of the flanges 42. For example, annealed titanium of a thickness between 0.1-0.3 mm of the flange shape shown in Fig. 4, would be sufficiently malleable for a surgeon to bend during surgery.

5 Figs. 7a and 7b show an alternative embodiment of the present invention. In this embodiment, the malleable flanges 42 are arranged to exit the implant package 22 from a lower surface of the package, but with the implant pedestal 44 still adapted to be positioned within a well formed in the skull. In this embodiment, the flanges 42 would preferably lie flush with the skull, and such a design may be more preferable for
10 younger children having thinner skin flaps over the implant.

Figs. 7c and 7d show a further variation of the embodiment of Figs 7a and 7b. In this embodiment, the malleable flanges 42 are also arranged to exit the implant package 22 from the lower surface of the implant package. In this embodiment, there is
15 no need to drill into the recipient's skull to form a bed for a pedestal 44, and the implant package can be quickly and securely fixed to the recipient's skull via skull attachment devices 43. In this embodiment, the implant package 22 is also provided with a domed profile to avoid the occurrence of tissue erosion.

20 Figs. 8a and 8b show yet another variation of the present invention. In this embodiment, the flanges 42 are attached to the uppermost surface of the implant package 22, with the implant package 22 positioned below the flanges 42. In this embodiment, a thin implant package can be sunk into the skull, ensuring that there is a minimal protuberance caused by the device.

25 Figs. 9a and 9b depict yet another embodiment of the present invention where the flanges 42 are attached at about the mid-line of the implant package 22, with the implant package 22 being typically partly buried in the skull. In this embodiment, the flange 42 would also preferably be positioned flush with the skull, while the bed or
30 well for the implant package would be fashioned in such a manner so as the antenna body is also partly sunk into the skull as shown. Such an embodiment does not require a pedestal 44 and ultimately provides a low profile implant that does not produce an unsightly protuberance and the problems associated therewith.

35 It should be appreciated that each of the flanges 42 shown in the above mentioned embodiments could be made from a plastic or elastomeric materials bonded

to the implant package 22. For example, the silicone rubber coating of the implant package 22 can be extended to create a silicone rubber flange which may be secured to the skull via appropriate means. Further, a plastic material, such as PTFE or polyurethane, can be embedded within the silicone rubber coating of the implant package 22 to form a flange. Such a device may also be attached to the implant package via a mechanical interlock. It may also be possible to make the flange of a composite or combination of materials. For example, a Dacron mesh may be used as a reinforcing structure to strengthen the silicone rubber coating. PTFE, polyurethane or carbon fibre materials may also be used as a reinforcing member.

10

By providing the flange made from a plastic or elastomeric material, it then becomes possible for the surgeon to remove or cut-off the flange during the surgical procedure should they not wish to use such a fixation method. This results in the fixation mechanism being an optional feature. Such a flange would also be easier to form and alter the shape thereof to more appropriately conform to the shape of the recipient's skull. Further, a flange made from a plastic or elastomeric material is softer than a metallic flange and will therefore be less prone to causing tissue erosion.

Figs. 10, 11a, 11b, 12a, and 12b depict yet another embodiment of the present invention. In this embodiment, the flanges 42 are detachable from the implant package 22. Each flange 42 is attached to the implant package 22 via lugs or clips 50 protruding from the side of the case of the implant package 22. The flanges 42 are received in the lugs or clips 50 and can be securely attached to the skull via appropriate skull attachment devices 43. This embodiment has the advantage that there is no need for a separate flange plate which adds thickness to the implant package. Further, the use of the flanges is optional, should the surgeon prefer not to use the flanges to secure the implant in place.

As is shown in Figs. 11a, 11b, 12a and 12b, this embodiment allows the implant to be sunk into the skull to varying depths as decided by the surgeon during surgery. Figs. 11a and 11b depict the implant positioned to a depth where only the pedestal 44 is sunk into the skull, with the detachable flanges 42 fixing the device in place through engagement with the lugs or clips 50 formed on the implant package 22. Figs. 12a and 12b depict the implant being positioned deeper within the skull bone, with the detachable flanges 42 engaging with the lugs or clips 50 to secure the device in place.

Fig. 13 depicts yet another embodiment of the present invention. In this embodiment, a detachable flange plate 55 is used instead of separate flange elements that are integrally fixed or detachably fixed as shown in previous embodiments. The detachable flange plate 55 extends over and across the implant package 22, with skull attachment devices 43 being used to secure the plate 55 and therefore the implant package 22 in position. As is shown in Fig. 13, the plate 55 could include a cut-out section 56 should an electrode be positioned on the implant package casing 22 (as is the case with some currently existing implants) such that body fluids can access the electrode. There may also be a need to provide washers 57 to assist in securing the plate to the skull via the skull attachment devices, especially if a non-metallic plate is used. The plate 55 can be malleable to conform with the desired shape of the recipient's skull, and the shape can easily be manipulated by the surgeon during surgery.

Figs. 14a and 14b depicts the plate in use. As can be appreciated, the shape of the plate can be easily manipulated to cater for variable depths of implantation of the package 22 into the skull.

The embodiment as shown in Fig. 13 has advantages in that the plate 55 is an optional feature, and should a surgeon decide that such a method of fixation is not suitable for the patient during surgery, then the surgeon can choose not to use the plate 55. Further to this, the plate 55 could be used with existing implants without any need to modify the design of present implant packages to accommodate such a securing mechanism. This is important, particularly in the case of implants utilising a ceramic or non-metallic casing, as these implants do not allow for metal flanges to be welded to the non-metallic casing.

As alluded to above, the plate 55 may be made of a non-metallic material, such as a biocompatible plastic since there is no need for welding of the plate to the implant package 22. Such a plate would overcome the need to provide a coating of silicone rubber to the surface of the plate to soften it and prevent tissue erosion. In this regard, the plate 55 could be made of a polyurethane or PTFE which are strong, relatively inelastic materials suited to this application. However, it should be envisaged that other plastics may also be used which exhibit the desired properties.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as
5 illustrative and not restrictive.

CLAIMS:

1. A medical implant for implantation within a body of a recipient, the medical implant comprising a hermetically sealed housing, said housing having at least one flange extending outwardly therefrom that is securable to tissue within the body of the recipient.
2. The medical implant of claim 1 wherein said at least one flange is securable to a surface of a bone within the recipient.
3. The medical implant of claim 2 wherein the implant is an implantable component of a tissue-stimulating prosthesis.
4. The medical implant of claim 3 wherein the tissue-stimulating prosthesis is a cochlear implant and the implantable component is a receiver/stimulator package of such an implant.
5. The medical implant of claim 2 wherein the housing is positionable on the surface of the bone of the recipient.
6. The medical implant of claim 2 wherein the housing is positionable within a bed or well formed in the surface of the bone of the recipient.
7. The medical implant of claim 1 wherein the housing has at least two flanges extending outwardly therefrom.
8. The medical implant of claim 7 wherein the housing has two flanges that extend in substantially opposite directions relative to each other.
9. The medical implant of claim 1 wherein at least one of said at least one flange extends from a first or upper surface of the housing.
10. The medical implant of claim 1 wherein at least one of said at least one flange extends from a second or lower surface of the housing.

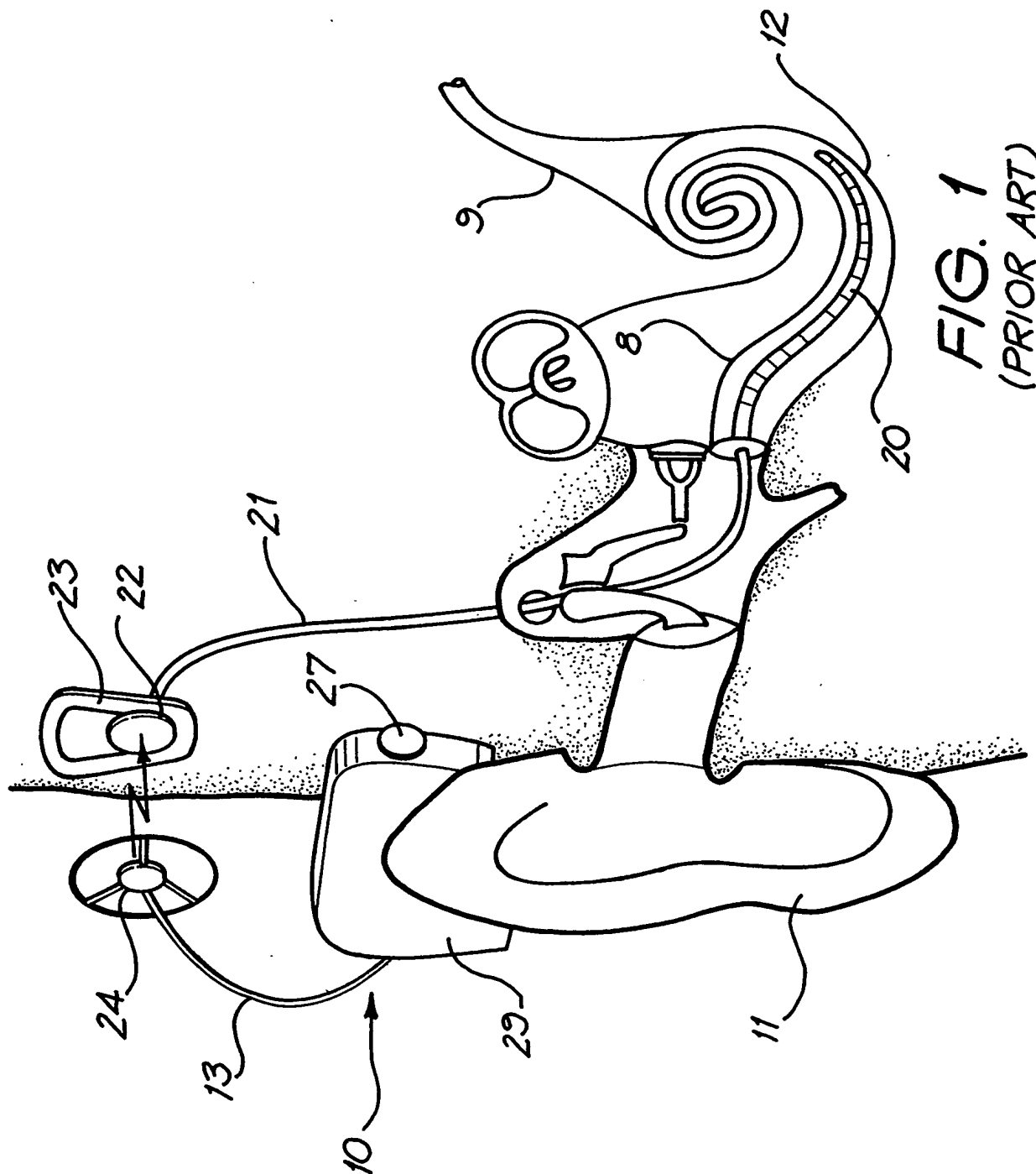
11. The medical implant of claim 1 wherein at least one of said at least one flange extends from the housing at a location between a first or upper surface of the housing and a second or lower surface of the housing.
- 5 12. The medical implant of claim 11 wherein said at least one flange extends outwardly from a location that is approximately midway between the first and second surfaces.
13. The medical implant of claim 1 wherein a plate is mounted to the housing and
10 said at least one flange extends outwardly from the plate.
14. The medical implant of claim 13 wherein said plate is removably or non-removably mounted to the housing.
- 15 15. The medical implant of claim 1 wherein said at least one flange is conformable to the tissue surface.
16. The medical implant of claim 15 wherein said at least one flange is formed of a malleable material.
- 20 17. The medical implant of claim 15 wherein said at least one flange has a thickness between about 0.1mm and 0.3mm.
18. The medical implant of claim 1 wherein said at least one flange is an integral
25 extension of the housing.
19. The medical implant of claim 1 wherein said at least one flange is formed separately and mounted to the housing.
- 30 20. The medical implant of claim 1 wherein said at least one flange is removably mounted to the housing.
21. The medical implant of claim 20 wherein said at least one flange or the housing is provided with engagement means that are engageable with the housing or flange,
35 respectively.

22. The medical implant of claim 21 wherein the engagement means comprises one or more clips on the housing that are engageable with the flanges.

23. The medical implant of claim 1 wherein said at least one flange has one or more
5 orifices passing therethrough that are adapted to receive a tissue fixation device.

24. A medical implant for implantation within a body of a recipient, the medical implant comprising a hermetically sealed housing, said housing having at least one flange extending outwardly therefrom that is securable and conformable to tissue
10 within the body of the recipient.

25. The medical implant of claim 24 wherein said at least one flange is formed of a malleable material.



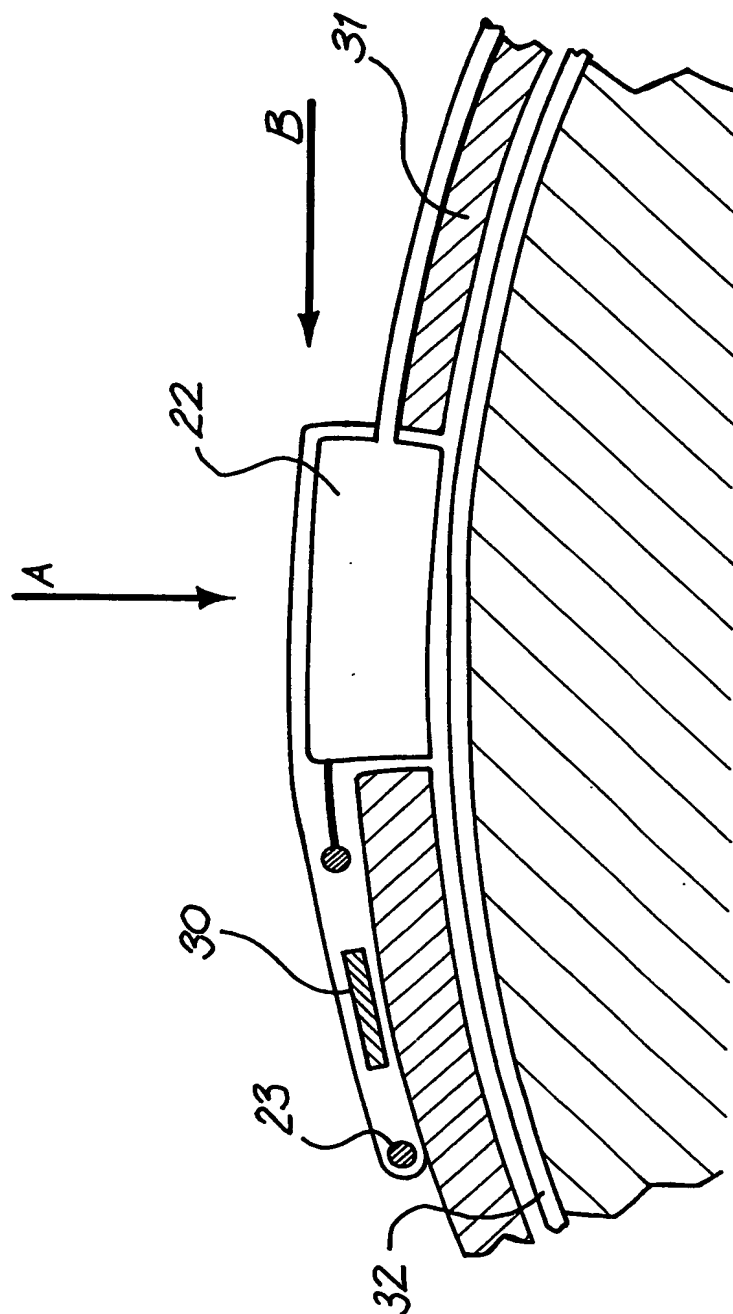


FIG. 2
(PRIOR ART)

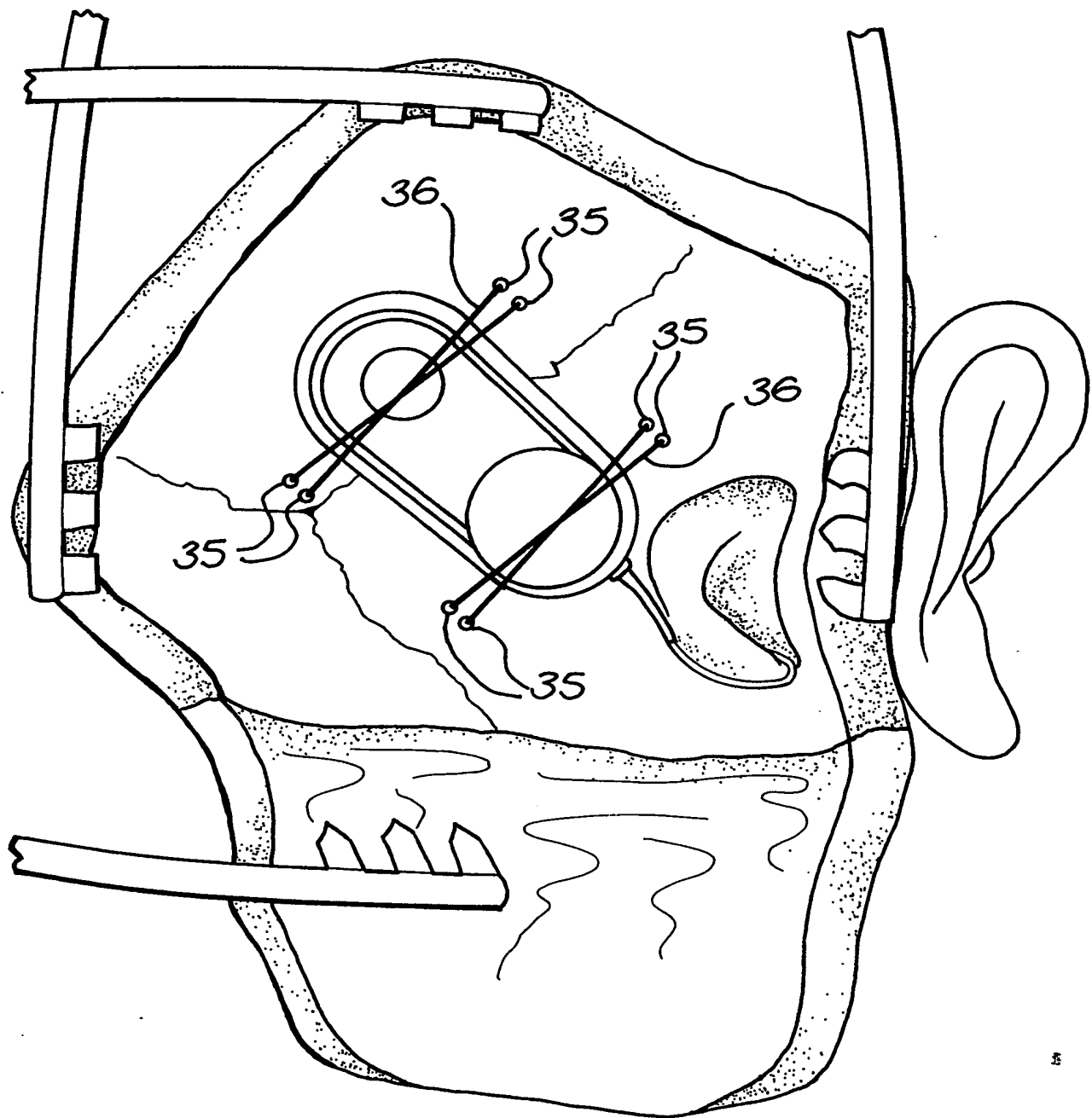


FIG. 3
(PRIOR ART)

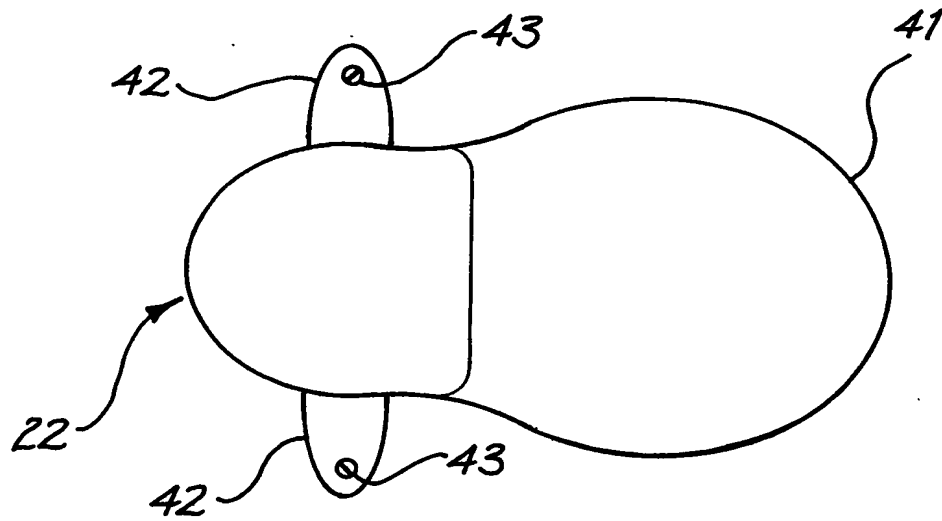


FIG. 4

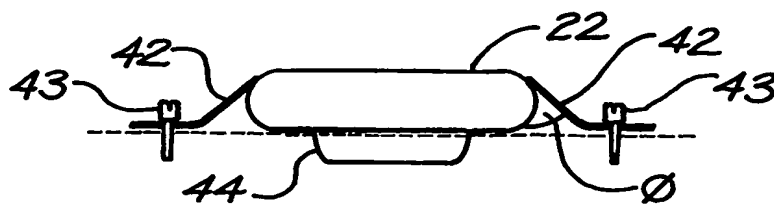


FIG. 5a

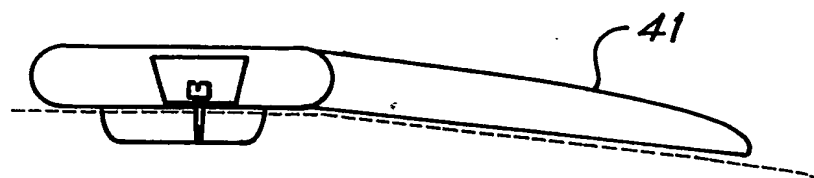


FIG. 5b

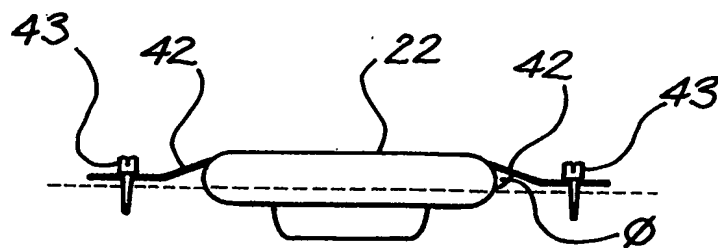


FIG. 6a

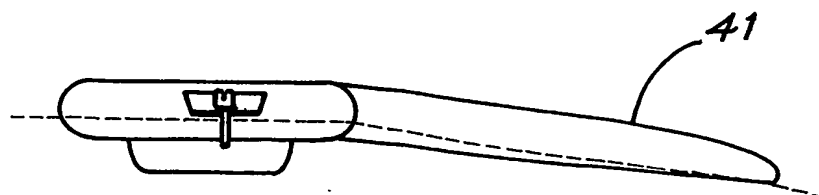


FIG. 6b

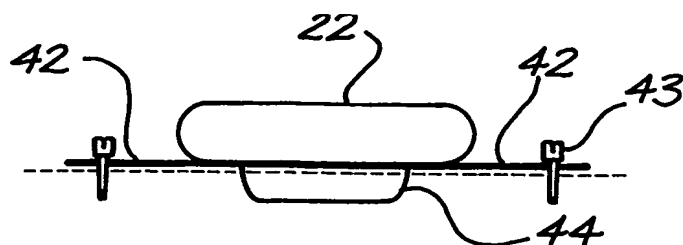


FIG. 7a

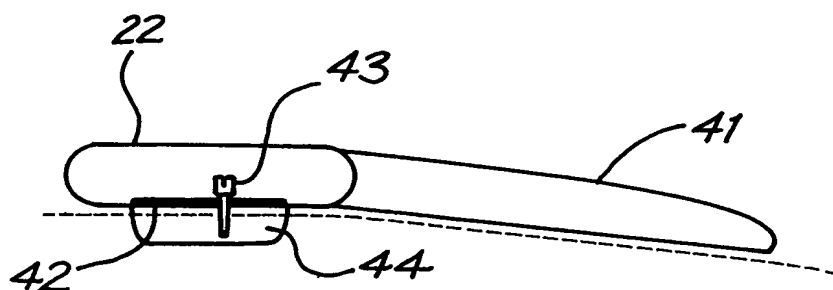


FIG. 7b



FIG. 7c

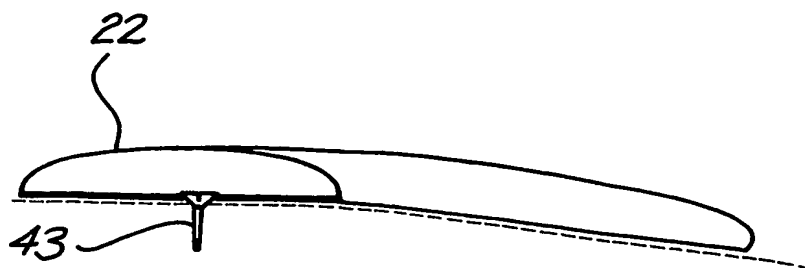


FIG. 7d

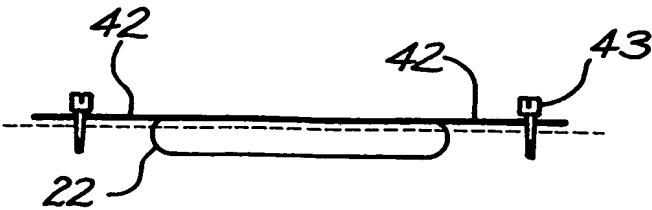


FIG. 8a

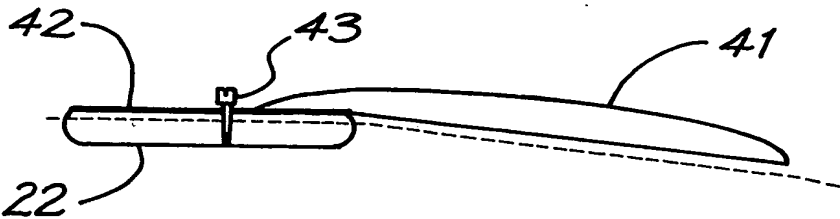


FIG. 8b

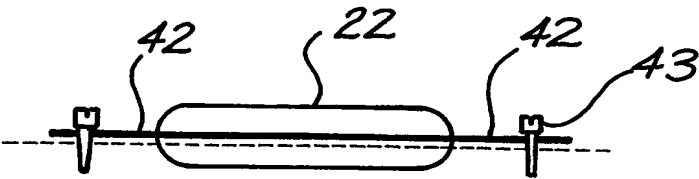


FIG. 9a

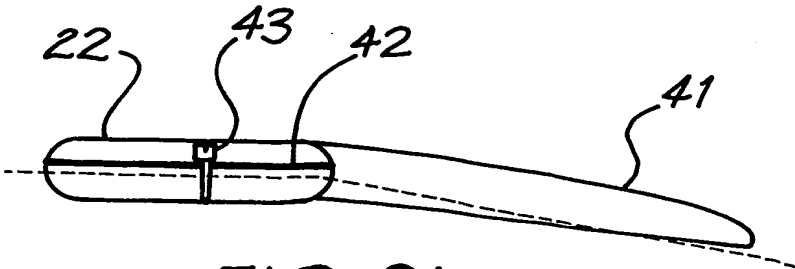


FIG. 9b

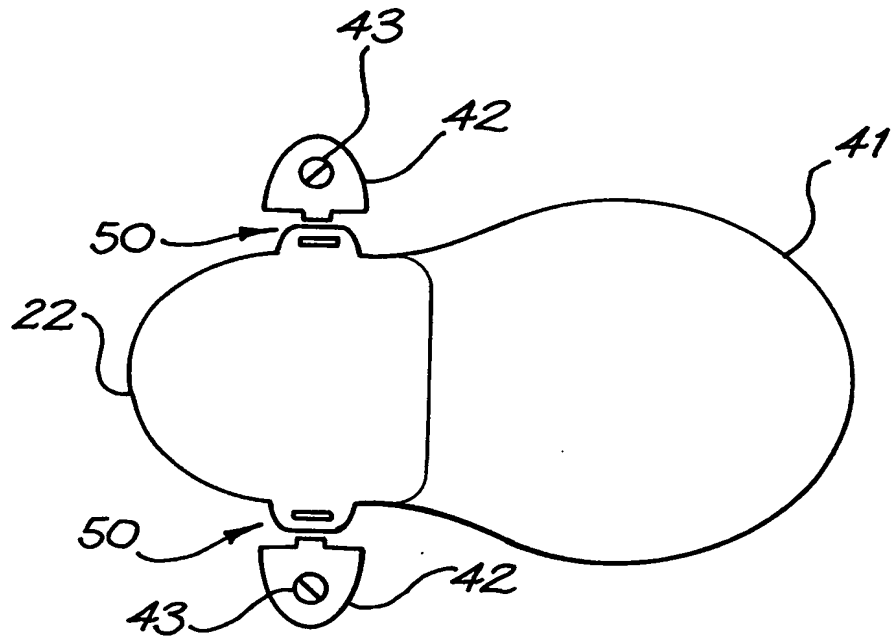


FIG. 10

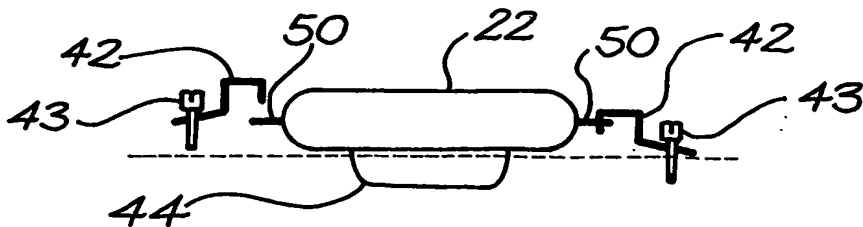


FIG. 11a

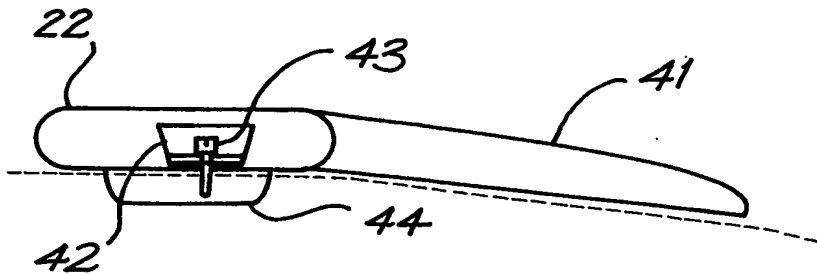


FIG. 11b

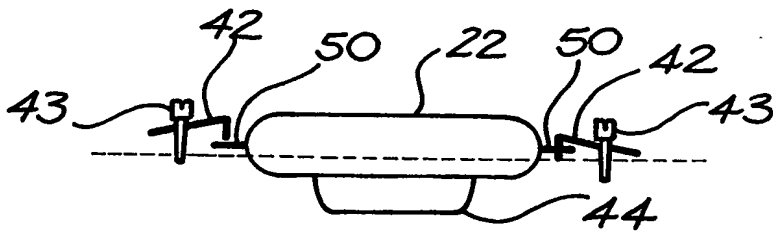


FIG. 12a

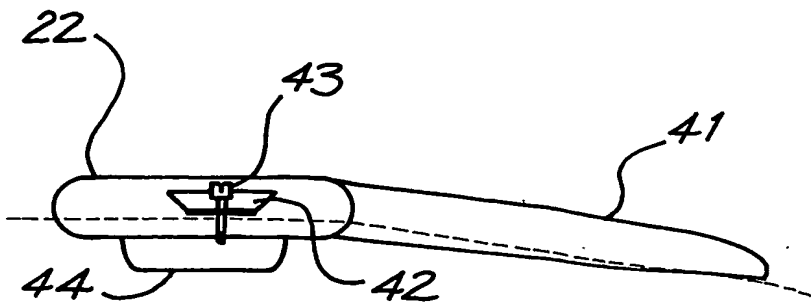


FIG. 12b

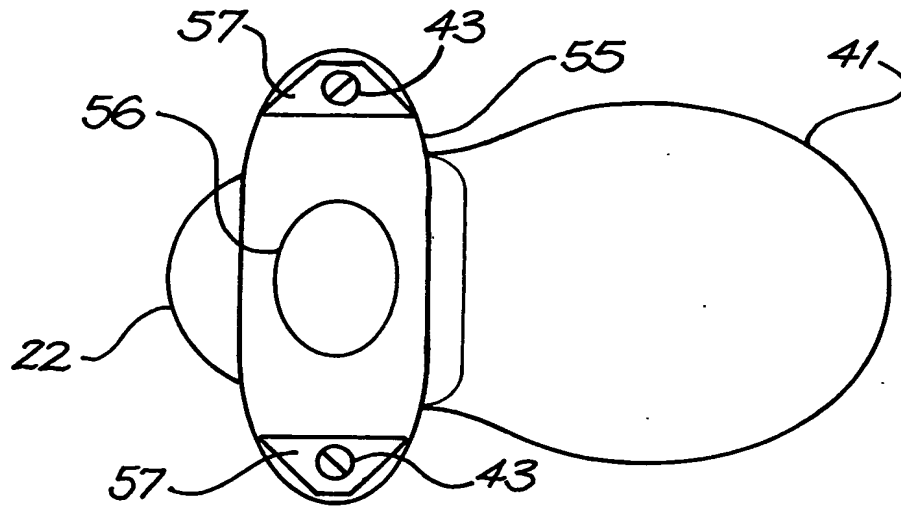


FIG. 13

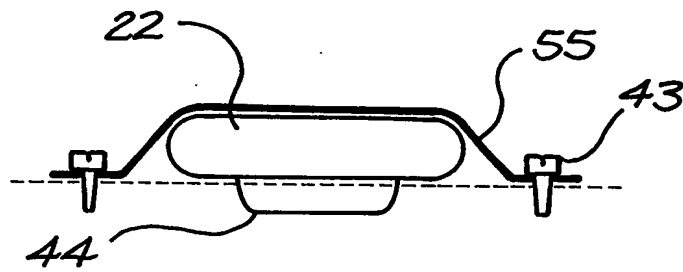


FIG. 14a

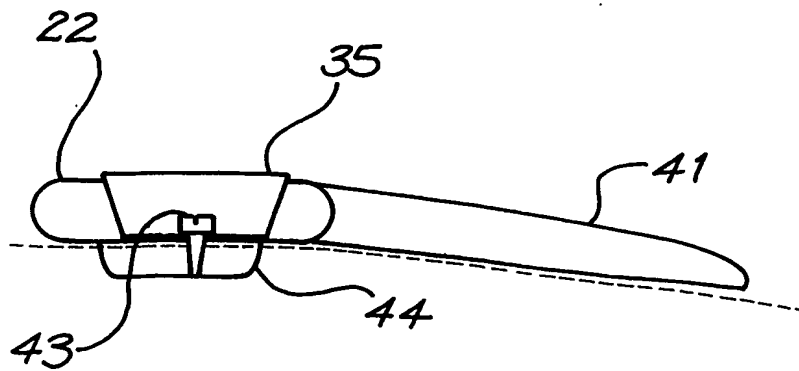


FIG. 14b

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/01004

A. CLASSIFICATION OF SUBJECT MATTER				
Int. Cl. 7: A61F 11/00, A61B 17/56				
According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols)				
Refer electronic databases consulted below				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)				
DWPI +keywords:implant, flange, housing and similar terms				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	US 5,906,635 A (MANIGLIA) 25 May 1999 figures 8 and 9	1-25		
X	US 6,427,086 B1 (FISCHELL et al) 30 July 2002 column 34 line 62 to column 35 line 56, figures 27 and 28	1-25		
A	WO 94/29932 A1 (COCHLEAR PTY LTD) 22 December 1994 Abstract			
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex				
<p>* Special categories of cited documents:</p> <table style="width: 100%;"> <tr> <td style="width: 50%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>
<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>			
Date of the actual completion of the international search		Date of mailing of the international search report		
18 September 2003		13 OCT 2003		
Name and mailing address of the ISA/AU		Authorized officer		
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		SUE THOMAS Telephone No : (02) 6283 2454		

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU03/01004

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
US	5906635	US	5558618
US	6427086	US	6161046
		EP	1145735
		EP	1145736
		US	6061593
		US	6128538
		US	6230049
		US	6354299
		US	6466822
		US	6480743
		US	2001051819
		US	2001056290
		US	2002002390
		US	2002072770
		US	2002077670
		US	2002099412
		US	2002169485
WO	9429932	AU	69650/94
END OF ANNEX			

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.